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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SIEW, JEFFREY

ART UNIT	PAPER NUMBER
1637	11

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,748	MACK ET AL.	
	Examiner	Art Unit	
	Jeffrey Siew	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 25-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 & 25-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19, 25-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,420,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-50 of US 6,420,108 are drawn to the method and product of displaying a mark at X,Y displaying information in response to user input which represents a species of the genus computer method and product claims of the instant application which are drawn to displaying a mark.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated Zhao et al (Gene Vol. 156 pp. 207-213 1995).

Claims 1-5 are drawn to displaying expression levels or compound concentration of two samples on a graph in which the first axis corresponds to expression level of first sample and the second axis is perpendicular to first axis and corresponds to expression level of second sample and a mark is displayed.

Zhao et al teach bioimaging analyzer system to compare the expression profiles of thousands of genes cDNAs) simultaneously . They teach the a high density cDNA filter analysis in which expression profiles of 2505 cloned human brain cDNAs (genes) were monitored (see whole document esp. Abstract). A quantitative analysis of the filter is performed using Fuji Bioimaging Analyzer BAS2000 System and automated quantification program AutoQuant. The final part is sequence analysis in which each clone is characterized by homology search in the GENBANK nucleotide Sequence Database (see page 208 & Figure 1). They applied the system for the comparative analysis of expression profile of the human cDNAs in brain. The expression profiles were illustrated on graphs by comparing the their scores from two tissues with Microsoft Excel (Microsoft) on a Macintosh personal computer(see page 210-211 and fig. 3). A mark for each gene is positioned relative to the expression levels in the two different samples.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 25-29 are rejected under 35 U.S.C. 102(b) as anticipated by (as recited previously) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhao et al (Gene Vol. 156 pp. 207-213 1995).

Claims 25-29 are drawn to a software product that contains code that displays on first axis expression level or compound in first sample, displays on second axis an expression level or compound in second sample, displays a mark whose position is relative to first or second axis.

Zhao et al teach bioimaging analyzer system to compare the expression profiles of thousands of genes cDNAs simultaneously . They teach a high density cDNA filter analysis in which expression profiles of 2505 cloned human brain cDNAs (genes) were monitored (see

whole document esp. Abstract). A quantitative analysis of the filter is performed using Fuji Bioimaging Analyzer BAS2000 System and automated quantification program AutoQuant. The final part is sequence analysis in which each clone is characterized by homology search in the GENBANK nucleotide Sequence Database (see page 208 & Figure 1). They applied the system for the comparative analysis of expression profile of the human cDNAs in brain. The expression profiles were illustrated on graphs by comparing the their scores from two tissues with Microsoft Excel (Microsoft) on a Macintosh personal computer(see page 210-211 and fig. 3). A mark for each gene is positioned relative to the expression levels in the two different samples. Although the reference is silent to the teaching of "code", it was well known and commonly practiced that Microsoft Excel (see page 211) is a software product containing code used to generate graphs. Through the use of this code, Zhao et al generated the graphs depicted in Figure 3 to compare the expression level of two different samples. Moreover, the computer used was a Macintosh computer(see page 211) as depicted in Figure 1. Although the reference is silent to the teaching of processor, memory and display, the personal computer inherently contains a display, microprocessor and memory in the form of RAM, ROM and hard disk.

In the alternative one of ordinary skill in the art would have been motivated to implement the Microsoft Excel program in code format to display the expression level in order to analyze various data inputs from various samples on different platforms. A program code provides versatility in allowing dynamic input to be analyzed. It would have been advantageous to implement analysis and display on code so that a large number of different samples would be analyzed especially over time. Moreover, the implementation on code would allow the analysis to be performed across different platforms and even different machines. It would have been prima facie obvious to implement the display of the expression levels through a computer code comprising code in order to analyze and display a constantly changing and new input across different platforms and machines.

Moreover, in the alternative one of ordinary skill in the art would have been motivated to to display the expression level on a computer system containing display, processor and memory in order to analyze various data inputs from various samples. A computer system provides excellent data storage and data manipulation capabilities. It would have been advantageous to implement analysis and display on a computer system so that a large number of different samples would be analyzed. It would have been prima facie obvious to implement the display of the expression levels on a computer system in order to analyze large amounts of data efficiently.

4 Claim 19 & 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (Gene Vol. 156 pp. 207-213 1995).

The teachings or suggestions of Zhao et al are described previously, briefly they teach bioimaging analyzer system to compare the expression profiles of thousands of genes cDNAs) simultaneously. They teach the a high density cDNA filter analysis in which expression profiles of 2505 cloned human brain cDNAs (genes) were monitored (see whole document esp. Abstract). A quantitative analysis of the filter is performed using Fuji Bioimaging Analyzer BAS2000 System and automated quantification program AutoQuant. The final part is sequence analysis in which each clone is characterized by homology search in the GENBANK nucleotide Sequence Database (see page 208 & Figure 1). They applied the system for the comparative analysis of expression profile of the human cDNAs in brain. The expression profiles were illustrated on graphs by comparing the their scores from two tissues with Microsoft Excel (Microsoft) on a Macintosh personal computer(see page 210-211 and fig. 3). A mark for each gene is positioned relative to the expression levels in the two different samples. Although the reference is silent to the teaching of "code", it was well known and commonly practiced that Microsoft Excel (see page 211) is a software product containing code used to generate graphs. Through the use of this code, Zhao et al generated the graphs depicted in Figure 3 to compare the

expression level of two different samples. Moreover, the computer used was a Macintosh computer(see page 211) as depicted in Figure 1. Although the reference is silent to the teaching of processor, memory and display, it was well known and commonly practiced in the art that personal computer contains a display, microprocessor and memory in the form of RAM, ROM and hard disk.

Zhao et al do not teach a third axis.

One of ordinary skill in the art would have been motivated to apply a third axis to Zhao et al display format in order to further compare the expression level in a third sample. It would have been advantageous to use a 3D format to compare three samples at the same time so that comparisons would be visually easier to interpret and would be performed simultaneously. It would have been prima facie obvious to apply a third axis to Zhao et al's display format in order to analyze more information at the same time.

5 Claims 6-18 & 30-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al (WO97/27317 21 July 1997) in view of Zhao et al (Gene Vol. 156 pp. 207-213 1995).

Claims 6-18 are drawn to claim 1 in which the expression level of expressed sequence is monitored.

Claims 30-42 are drawn to computer product comprising code for displaying a first axis corresponding to expression level of first axis, code for displaying a first axis corresponding to expression level of first axis and code for displaying a mark , a computer readable storage medium for storing codes.

Lockhart et al teach a method of detecting nucleic abundances or concentrations (e.g. expression levels) between two or more samples (see whole document esp. abstract). They teach the simultaneous monitoring of the expression of a multiplicity of genes using perfect match

probe and mismatch probes (see page 5,12,47 & esp. 49-50). They teach that expression monitoring would be useful for both drug safety and toxicology screenings (see page 230) and monitoring various genes in response to defined stimuli such as drugs (see page 22). They teach that monitoring of gene expression may be performed using a computer system running a software program that includes computer code incorporating analysis of hydridization intensities of the screens(see page 90 & Figure 6-8). They teach a method of comparing expression level using the hybridization intensities between the perfect match and mismatch probes (see page 93-101 & Figure 9-10B). They compare the hybridization intensity difference and ratio of the perfect match and mismatch probes with a threshold. The values NPOS, NNEG and LR are calculated for each pair of probes. The analysis is repeated to calculate the average of the differences. They teach that oligonucleotide pairs that show the greatest differential hybridization between two samples can be identified by sorting the observed hybridization ratio and difference values. Based on identified oligonucleotide pair sequences, a gene can be searched for in sequence databases such as GENBANK (see page 128-9). They also display the results in a graph showing differential expression between samples (see Figures 16-17).

Lockhart et al do not teach presenting expression level information by displaying on a first axis representing the expression level in a first sample, displaying on second axis representing the expression level in the second axis and displaying a mark relative to the two axes.

Zhao et al teach bioimaging analyzer system to compare the expression profiles of thousands of genes cDNAs) simultaneously . They teach the a high density cDNA filter analysis in which expression profiles of 2505 cloned human brain cDNAs (genes) were monitored (see whole document esp. Abstract). A quantitative analysis of the filter is performed using Fuji Bioimaging Analyzer BAS2000 System and automated quantification program AutoQuant. The final part is sequence analysis in which each clone is characterized by homology search in the

GENBANK nucleotide Sequence Database (see page 208 & Figure 1). They applied the system for the comparative analysis of expression profile of the human cDNAs in brain. The expression profiles were illustrated on graphs by comparing the their scores from two tissues with Microsoft Excel (Microsoft) on a Macintosh personal computer(see page 210-211 and fig. 3).

One of ordinary skill in the art would have been motivated to display the comparative expression levels of genes as in Zhao et al's to Lockhart et al's analysis technique in order to compare the gene expression between two different samples. Zhao et al's display format allows easy visualization of the many different expressions of genes between two samples. It would have been prima facie obvious to construct a graph with an axis representing the gene expression in one sample and another axis representing the gene expression in a second sample in order to compare the differential gene expression between the different samples.

6. The response filed 5/20/03 has been fully considered and deemed not persuasive. The response states that at the time of producing the graph Zhao et al did not know the sequence of cDNA sequences used in the probes. First the claims do not limit as to when the sequence of clones is determined. Second Zhao et al determine information in detecting differential expressed cDNAs between fetal and adult. As the claims read broadly on any information, the art rejections are maintained. (see page 211 & Figure 3).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

JEFFREY SIEW
PRIMARY EXAMINER

July 13, 2003